

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

GE HEALTHCARE BIO-SCIENCES AB, GE
HEALTHCARE BIO-SCIENCES
CORPORATION, and
GENERAL ELECTRIC COMPANY,

Plaintiffs,

v.

BIO-RAD LABORATORIES, INC.,

Defendant.

Civil Action No. 14-CV-7080-LTS

Hon. Laura Taylor Swain

REDACTED

**DECLARATION OF NIGEL DARBY IN SUPPORT OF PLAINTIFFS' MOTION FOR A
PRELIMINARY INJUNCTION**

I, Nigel Darby, hereby declare as follows:

1. I make this declaration in support of Plaintiffs GE Healthcare Bio-Sciences AB's ("Bio-Sciences AB"), GE Healthcare Bio-Sciences Corporation's ("Bio-Sciences Corp.") and General Electric Company's ("General Electric Co.") (collectively, "GE") Motion for a Preliminary Injunction. I have personal knowledge of the facts stated herein, and if called upon as a witness, could and would testify competently hereto.

2. I am employed by GE Healthcare Bio-Sciences AB, a GE business, which maintains protein separations research, development, and manufacturing facilities. I have worked for GE Healthcare Bio-Sciences AB in Uppsala, Sweden since April 2003, and my present job title is Vice-President, Bio-Process. As Vice-President, Bio-Process, I am responsible for sales, marketing, R&D of products for the bio-process business, which includes the ÄKTA product line.

3. Bio-Sciences AB is the assignee of U.S. Patent No. 8,821,718 (the “’718 patent”). Bio-Sciences AB granted to Bio-Sciences Corp., effective September 2, 2014, a royalty-free exclusive license to sell products in the United States under the ’718 patent.

4. Bio-Sciences AB and its predecessor companies have developed, manufactured, and sold protein purification-related technologies since the 1950s.

5. Protein purification is an important aspect of biopharmaceutical research and manufacturing. Protein purification is, generally speaking, a series of processes intended to isolate a single or small number of proteins from a complex mixture. Such isolation is essential for the characterization of the function, structure, and interactions of proteins of interest.

6. Protein purification can be roughly divided into an analytical and preparative method: the analytical method aims to detect and identify proteins in a mixture, while the preparative method aims to produce large quantities of proteins for purposes such as industrial use.

7. Preparative protein purification can be accomplished through any number of means, including through a liquid chromatography (“LC”) system. Such a system utilizes pumps to pass a pressurized liquid solvent containing a sample mixture through a column filled with a protein separation substance, for example, an adsorbent material. (Adsorption refers to the adhesion of atoms, ions, or molecules from a gas, liquid, or dissolved solid to a surface.) When each component interacts with the adsorbent material, it causes different flow rates and separates the components as they flow out of the column.

8. One important line of products developed by Bio-Sciences AB is its protein purification systems marketed and sold under the trade name ÄKTA™. Two of Bio-Sciences AB’s earliest ÄKTA systems were the ÄKTAexplorer system, launched in 1996, and the

ÄKTApurifier system, launched in 1997. The quality and reliability of both systems were well-regarded in the preparative protein purification market.

9. Beginning in 2003, Bio-Sciences AB began developing a new modular design for preparative protein purification systems that would enable researchers to more quickly, easily, and cost-effectively purify proteins by allowing for interchangeable placement of the fluid handling units and the separation of fluidics and non-fluidics sections.¹ The basic idea underlying the modular design concept was to organize a complex system as a set of distinct components that could be manufactured independently and then plugged into the fluid handling panel of the instrument. Bio-Sciences AB believed that such a modular design could not only simplify researchers' work, but also give researchers a flexible option for expanding and tailoring their purification capabilities as the research progresses. Additionally, Bio-Sciences AB believed that a modular system could be more easily upgraded without need for add-on equipment and offered a system with better ergonomics and a more user-friendly design. Ideally, Bio-Sciences AB wanted a modular system that could be fully automated, easy to use, highly efficient, and with easy interchangeability between all of its components and modules.

10. For the next six years, Bio-Sciences AB devoted substantial resources into the development of a modular protein purification system in accordance with its goals. The project required a complete overhaul of both software and instruments. To achieve its goals, Bio-Sciences AB committed a significant part of its R&D team in Uppsala and manufacturing team in Umea, between 200-250 employees, and conducted extensive market research. Development of the new designs cost Bio-Sciences AB over \$100 million.

¹ For convenience, this declaration uses various shorthand terms such as "modular system", "modular protein purification system", "modular design", and "modular panel design" when referring to Bio-Sciences AB's patented system.

11. In August 2009, Bio-Sciences AB launched its flagship modular preparative protein purification system, the ÄKTA avant system. The ÄKTA avant system is a distinctive modular system that offers a large range of options to allow flexibility in purification of proteins. ÄKTA avant is designed to meet the needs of process developers and can be customized with a number of flexible module options to extend the hardware functionality. Among other things, this system also provides for separation of fluidics sections (external to the housing) from non-fluidics sections (internal to the housing). The ÄKTA avant system currently is available in two versions. ÄKTA avant 25 is optimized for media screening and method optimization using small columns. ÄKTA avant 150 is designed for scaling up to larger columns, as well as fine tuning and robustness testing of the optimized process. At the time of its launch, the ÄKTA avant system was the only chromatography system on the market to offer a modular panel design allowing for interchangeable placement of the fluid handling units and which separated the fluidics section from the non-fluidics section.

12. In August 2012, Bio-Sciences AB launched a second modular preparative protein purification system, the ÄKTA pure system, after spending considerable effort and expense to improve upon the ÄKTA avant design. The ÄKTA pure system is a flexible and intuitive chromatography system for fast purification of proteins, peptides, and nucleic acids from microgram to gram levels of target product. The ÄKTA pure system can be tailored to a customer's precise needs through a broad selection of hardware options from valves and tubing to monitors and fraction collectors.

13. The year after its launch, the ÄKTA pure system was nominated as the best new separations product introduced on the market in 2012 by SelectScience, an independent, expert-led scientific review source for the worldwide scientific community.

14. Bio-Sciences AB has expended considerable effort and expense to train researchers on the use of modular protein purification systems, and in particular, the use of the ÄKTA avant and ÄKTA pure systems. Bio-Sciences AB's efforts and investments have been directed towards education about the scalability and productivity of the unique design of the ÄKTA avant system, and the flexibility of the intuitive design of the ÄKTA pure system.

15. In or about March 2010, Bio-Rad Laboratories, Inc. ("Bio-Rad") purchased an ÄKTA avant system.

16. That same year, Bio-Rad hired Shawn Anderson, a former Bio-Sciences Corp. employee. From approximately 2000 to 2008, Shawn Anderson was employed as a senior account manager at Bio-Sciences Corp., during which time he gained insight into the development and launch strategy of the ÄKTA modular protein purification systems, having been a member of the products' concept teams. Before that, Anderson was employed by Pharmacia (currently GE Healthcare AB) for seven years.

17. On October 26, 2012, Bio-Rad employee Paul Johnson emailed GE employee Vivian Tseng, with a cc to Bio-Rad employees Michael Urban and Richard Lee, requesting an upgrade for the ÄKTA avant system that Bio-Rad had purchased. Mr. Urban "replied to all," stating in his reply email that he was "very skeptical that [Mr. Johnson] will get much traction with [Ms. Tseng] with [his] email signature indicating [he is] a [Bio-Rad] lab chromatography marketing specialist. Mr. Urban went on to state that Bio-Rad purchased the ÄKTA avant system "under the pretense that it was being used to support protein process development." Mr. Urban further stated that he "would like to keep the story going so that we could service on our akta when needed." A true and correct copy of the email exchange is attached as Exhibit A.

18. In January 2013, Bio-Rad began marketing and selling a modular protein purification system under the brand name NGC™.

19. Bio-Rad's NGC system is strikingly similar to Bio-Sciences AB's ÄKTA pure system.

20. Beginning prior to launch, Bio-Rad marketed, promoted, and sold the NGC system, and has continued to market, promote, and sell the NGC system, including to accounts that presently use ÄKTA systems. Bio-Rad also targeted Bio-Sciences AB's ÄKTA systems in a series of marketing videos uploaded to YouTube. The YouTube videos are available at <http://www.youtube.com/watch?v=jXJS7-eCd5A>, <http://www.youtube.com/watch?v=fytxs4M5zmc>, <http://www.youtube.com/watch?v=FZMZihPmv5s>, <http://www.youtube.com/watch?v=v9DtSSpoB70>, and <http://www.youtube.com/watch?v=J57Q0HC7c4g>.

21. The NGC and ÄKTA systems are the only protein purification systems featuring the modular panel design allowing for swapping of interchangeable modules that are currently marketed or sold for the purpose of preparative protein purification in the United States. Thus, they are direct competitors.

22. I am aware that Bio-Rad has sold [REDACTED] of the NGC system worldwide covering [REDACTED] customers, primarily in the academic market. In most of these instances, GE lost a sale of an ÄKTA pure system. I am aware of specific instances where GE lost sales of the ÄKTA pure system to Bio-Rad's NGC system. These lost sales include sales to Drexel University, Georgia State University, University of California at Berkeley, University of Illinois, Cornell University, Case Western Reserve

University, University of Iowa, Medical College of Wisconsin, and University of Georgia. Many of these lost sales are the result of Bio-Rad pricing its NGC system lower than the ÄKTA pure system. Additionally, I am aware that Bio-Rad offers free or discounted “add-ons” to attract customers, such as a free second year warranty and free software.

23. Since Bio-Rad launched its NGC system, Bio-Sciences AB’s pricing of its ÄKTA pure system has decreased [REDACTED] in the United States.

24. The continued manufacture, sale, and use of the NGC system threatens Bio-Sciences AB’s future growth by preventing Bio-Sciences AB from gaining the first mover advantage that it needs, especially to strengthen its presence in the academic market.

25. Bio-Rad’s aggressive marketing of its NGC system, particularly in the academic market, has damaged and, unless enjoined, will continue to damage Bio-Sciences AB’s reputation as an innovator and leader in the field of modular preparative protein purification technology.

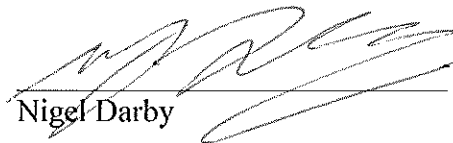
26. Bio-Rad also offers a suite of complementary products, such as a range of chromatography columns that compete with GE’s chromatography column offerings, which Bio-Rad markets and sells with the NGC System to GE’s customers.

27. GE had begun to see a return on its investment prior to the launch of the Bio-Rad NGC system, as acceptance of the design has increased in the preparative protein purification market, and as sales began to grow. Bio-Rad’s introduction of the NGC system has caused GE to lose sales. If Bio-Rad is allowed to continue its sales of the NGC system, GE believes it will continue to lose sales and that it will suffer further price erosion of its ÄKTA systems.

28. The ÄKTA avant and ÄKTA pure systems are sufficient to meet the needs of the preparative protein research community. Moreover, GE has the manufacturing capacity to increase production of both systems to meet all demand currently being met by the NGC system.

I declare under the laws of the United States of America and penalty of perjury that the foregoing is true and correct.

Executed this 9 day of September, 2014, in Uppsala, Sweden


Nigel Darby